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HOUSE COMMITTEE ON GOVERNMENT REFORM

HEARING ON

FOOD AND DRUG ADMINISTRATION'S OVERSIGHT AND REGULATION OF THE REPROCESSED SINGLE-USE MEDICAL DEVICE INDUSTRY

SEPTEMBER 26, 2006

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Good morning, Mr. Chairman and Members of the Committee. My name is Stephen J. Ubl, and I am the President and CEO of the Advanced Medical Technology Association (AdvaMed). AdvaMed is pleased to present testimony at this House Committee on Government Reform hearing on the Food and Drug Administration's (FDA) oversight and regulation of the reprocessed single-use medical device industry.

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent of the health care technology purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

We appreciate the attention that Congress has given through legislation to the regulation of single use devices that are reprocessed for multiple uses over the last few years. We continue to monitor the steps FDA is taking to implement these provisions and provide input to the Agency, and my testimony details our comments on these efforts.

Reprocessing of Single-Use Medical Devices

The reprocessing of a single use device can present a serious risk to patients if it does not result in a product that is as safe and effective as that of the original manufacturer. Single use devices are designed and manufactured for one use only in a single patient and are intended by the original equipment manufacturer (OEM) to be disposed of permanently after use. Their use has been reported to reduce the risk of nosocomial infections.[1] Single use devices are designed for optimal performance and safety under their intended conditions of use – not ease of cleaning. They typically have characteristics that make them extremely difficult to effectively clean and resterilize, including the fact that the devices have small, difficult to access areas, such as long, narrow lumens, acute angles, crevices, coils and joints, reinforcing meshes and rough, porous or occluded surfaces. These inaccessible areas create barriers to cleaning and allow for the collection of organic matter, such as blood, feces, respiratory secretions and gastric mucin.

Single use devices are not designed to – and may fail to – withstand the harsh conditions (e.g., exposure to solvents and extreme temperatures) encountered during reprocessing. Reprocessing of a previously used single use device may also seriously compromise its safety and effectiveness and even destroy some single-use devices.

For these and other reasons, AdvaMed strongly supported the reprocessing provisions in the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) which mandated new and stronger FDA regulatory requirements for reprocessed single use devices. In MDUFMA, for

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1 For example, see the following studies: **1)** Jernigan JA, Siegman-Igra Y, Guerrant RC, Farr BM. 1998. A randomized crossover study of disposable thermometers for prevention of Clostridium difficile and other nosocomial infections. Infect Control Hosp Epidemiol. 19(7): 494-9. **2)** Nosocomial Hepatitis B virus infection associated with reusable fingerstick blood sampling devices – Ohio and New York City, 1996. MMWR Weekly, March 14, 1997/46(10): 217-221. **3)** Brooks SE, Veal RO, Kramer M, Dore L, Shupf N, Adachi M. February 1992. Reduction in the incidence of Clostridium difficile-associated diarrhea in an acute care hospital and a skilled nursing facility following replacement of electronic thermometers with single-use disposables. Infect Control Hosp Epidemiol. 13(2): 98-103.

510(k) devices (including exempt Class I and II 510(k) devices[2]), Congress required that reprocessors submit cleaning, sterilization and functional performance data to FDA to "demonstrate that the [reprocessed] device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification."[3] For PMA devices, Congress established a new type of application – a "premarket report" – specifically tailored to reprocessed devices, that must meet all the requirements of a premarket approval application in addition to cleaning, sterilization and functional performance validation data "that demonstrates that the reasonable assurance of the safety or effectiveness of the device will remain after the maximum number of times the device is reprocessed as intended by the person submitting such report." [4] For PMRs, MDUFMA also provided FDA with explicit authority to require any other additional data and information needed to determine reasonable assurance of safety and effectiveness for the reprocessed device.[5]

Adverse Events Involving Reprocessed Single Use Devices

AdvaMed became aware of two adverse events involving reprocessed single use devices for which FDA had failed to require supplemental validation submissions (SVSs). We submitted these comments to FDA's reuse docket on September 30, 2004[6]. Specifically, a cardiovascular surgeon cut a patient's heart when a reprocessed heart positioner – used to manipulate the heart for access to vessels during beating heart bypass and other cardiac surgical procedures – failed to properly hold the heart during a by-pass procedure. The surgeon was forced to repair the laceration, exposing the patient to excessive bleeding and a prolonged procedure that posed additional risks to the patient (e.g., potential for compromised heart hemodynamics and infection). The foam gasket used on the suction cup to grasp the heart had decomposed due to reprocessing.

In another case, a reprocessed endoscopic vein harvesting system failed when a piece of shrink tubing broke free of the device and became lodged in a patient's leg. In this case, the surgeon was forced to 'fish' the dislodged part out of the patient's leg exposing the patient to excessive bleeding and a prolonged procedure. OEM failure analysis of the returned device found that the shrink tubing that broke free had deteriorated due to multiple sterilization cycles.

Both of these adverse events illustrate a key issue with respect to reprocessing. In many instances, surgeons are unaware that the devices they are using are reprocessed. In this case, the user or user facility returned the device to the OEM for failure analysis because they did not identify the device as one that was reprocessed.

AdvaMed was pleased when FDA announced in September 2005 that reprocessors would be

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2 Prior to MDUFMA, FDA did not require reprocessors to submit 510(k)s for original equipment manufacturer Class I and Class II single use devices that were exempt from submitting 510(k)s.

3 Section 302(b) of H.R. 5651, the Medical Device User Fee and Modernization Act of 2002

4 Section 302(c) of H.R. 5651, the Medical Device User Fee and Modernization Act of 2002.

5 Section 302(c) of H.R. 5651, the Medical Device User Fee and Modernization Act of 2002.

6 See September 30, 2004 AdvaMed Comments to Docket No. 03N-0161: Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data and Docket No. 02N-0534: Medical Device User Fee and Modernization Act (MDUFMA)

required to submit supplemental validation submissions for these two specific types of reprocessed devices. AdvaMed had written to FDA in August 2003 and again in September, 2004 to urge that validation data be required for positioners. The validation submissions for endoscopic accessories and heart positioners were and are due June 29, 2006 and December 29, 2006 respectively.

On June 29, 2006, AdvaMed wrote FDA[7] to enquire about FDA's plans for notifying hospitals if the validation submissions for these products were not received by FDA's deadlines and what, if any action, FDA planned to take regarding any of these reprocessed devices still on hospital shelves on those dates. In a September 5, 2006 communication to AdvaMed, FDA indicated that notifications to reprocessors for these products would be determined on a case-by-case basis and would depend on previous correspondence to the firm and the reprocessor's inspectional history. FDA indicated it would evaluate the risk to the health for the users and patients to determine the appropriate notification to the community for product remaining on hospital shelves.

We note our disappointment regarding FDA's response to the Chairman and the Ranking Member's questions about reprocessor adverse events (AEs). First, AdvaMed specifically brought the above-referenced adverse events to FDA's attention during the same timeframe (September 30, 2004) in which FDA has said it determined there were no adverse events related to the reprocessing of a single use device (October 22, 2003 through December 13, 2005). Secondly, Secondly, FDA's response ignores the fact that the OEM devices worked the first time for their intended single use *and* that the 176 adverse events would not have occurred if the single use devices had not been reprocessed and reused.

AdvaMed Implementation Concerns Shared with FDA

AdvaMed has closely monitored and has submitted multiple comments on FDA's implementation of the MDUFMA reprocessing provisions, and some of the comments we have submitted to the FDA are detailed below.

FDA's Bundling Policy

Prior to MDUFMA, FDA allowed one reprocessor to gain clearance for over 4,000 devices on the basis of just eleven 510(k)s. Bundling – under which FDA allows reprocessors to bundle multiple single use devices from different original manufacturers into a single submission – has continued to be an issue in MDUFMA implementation. FDA reported at its November 2004 MDUFMA Stakeholder meeting that 44 reprocessor submissions accounted for 1,800 different devices.

AdvaMed has objected to reprocessor bundling for multiple OEM single use devices. Even though the single use device type is the same, each manufacturer has a unique design for their device. Manufacturers are also likely to use different materials, and different manufacturing and engineering processes. As a result, different OEM devices may react differently to cleaning and re-sterilization even though they are the same device type. These differences may also affect the number of times the single use device can be reused. In fact, FDA's own laboratories have

7 See June 29, 2006 AdvaMed Comments to Docket No. 2003N-0161: Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data.

previously concluded that the decision to reuse a single use medical device is not a "category" decision but rather a "model specific" decision.[8] FDA is ignoring the conclusion of its own investigation of reuse when it presumes these technological differences do not preclude bundling.

FDA's Use of Review Prioritization Scheme

MDUFMA required FDA to identify reprocessed devices types (both exempt and non-exempt) for which reprocessors would be required to submit validation data on cleaning, sterilization and functionality. To identify reprocessed devices requiring validation data, FDA relied on the Review Prioritization Scheme (RPS) – a process FDA itself had previously criticized as potentially requiring "subjective responses" and being difficult to use to make consistent determinations.[9] AdvaMed believed Congress intended the Spaulding criteria to be the primary mechanism to identify reprocessed single use devices requiring validation data. Use of the RPS resulted in only 16 device types out of 126 exempt reprocessed device types having to submit validation data and only 53 device types out of a total of 228 non-exempt devices having to submit validation data. As a result, FDA has reviewed validation data for just a small subset of all reprocessed single use devices.

FDA Significantly Extended Validation Data Submission Deadlines

In April, 2003, FDA identified reprocessed single use devices that would be required to submit validation data and indicated that reprocessed 510(k) devices would have to submit "validation data for these devices by January 30, 2004, *or marketing of these devices must cease* [emphasis added]."[10]

In mid-February 2004, AdvaMed learned that reprocessers had failed to submit validation data – information and data reprocessors claimed to have all along – for the vast majority of the reprocessed single use devices subject to the January 30, 2004 deadline. AdvaMed was concerned that the failure of reprocessors to meet the deadline suggested that reprocessors: (1) either did not have the data or (2) had determined the data was inadequate to support continued reprocessing. AdvaMed believed that continued distribution of these devices represented an unreasonable risk to patients.

It is also important to note that MDUFMA merely established the requirement for *review* of validation data – not the requirement for the *existence* of the data. The Quality System Regulation (QSR) which applies to all manufacturers requires the existence of the data. The QSR requires that all manufacturing processes be validated. Importantly, in 1998, FDA confirmed in response to a September 5, 1997 citizen petition filed by AdvaMed (then HIMA)

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8 Brown SA, Merritt K, Woods TO, Hitchins VM. 2001. The effects of use and simulated reuse on percutaneous transluminal coronary angioplasty balloons and catheters. Biomedical Instrumentation & Technology. 312-322.

9 See FDA's February 2000 draft guidance laying out the RPS scheme, entitled "*Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme.*" FDA noted the scheme was subjective: "It is important to note that many of the questions asked in the flowcharts may require subjective responses." FDA also acknowledged the difficulty of using the RPS to make consistent determinations: "Despite the possibility of different interpretations, FDA has *tried* [emphasis added] to make consistent categorizations across all SUD types."

10 See April 30, 2003 *Federal Register* (FR) Notice #FR03-10413.

that reprocessors were considered manufacturers under FDA's Quality System regulation[11] thereby confirming that reprocessors were required to have such data. In 2000, Mr. Vern Feltner, representing the Association of Medical Device Reprocessors (AMDR) emphasized in verbal and written testimony before the House Commerce Subcommittee on Oversight and Investigations that "Reprocessors must comply with FDA QSRs just like manufacturers."[12]

Unexpectedly, FDA subsequently extended the validation submission deadline for reprocessors by an additional 90 days despite its statement in June 2004 in MDUFMA reprocessing implementing guidance that "we believe that manufacturers should have this validation information readily available since the reprocessed device(s) are currently being marketed and such data should have been developed and maintained as part of the Quality System requirements (21 CFR Part 820)."[13] At the time of FDA's extension, approximately 20 percent of the SVSs – for products currently on the market – had already been issued Not Substantially Equivalent (NSE) determinations by FDA.

The fact that 5½ years later reprocessors could not provide the validation data to FDA by the MDUFMA deadline suggests reprocessors did not have validation processes in place.

AdvaMed believed that FDA's decision extended the exposure of patients to products reprocessed with inadequate manufacturing controls.

Fifty Percent of Validation Submissions Contained Inadequate Data

In July 2004, AdvaMed learned that of the validation submissions received by FDA, approximately 20 percent had been deemed by FDA as non-substantially equivalent (NSE) to the original 510(k) held by the reprocessor either because the reprocessor failed to submit the required information or because the data were found to be inadequate and unable to be reviewed by FDA.

At FDA's November 2004 MDUFMA Stakeholder meeting, FDA announced that the NSE/withdrawn rate had increased to nearly 50 percent. It is important to note that this NSE/withdrawn rate is just for the small subset of reprocessed devices that were required to submit validation data.

The rate is much higher than the annual NSE rate provided in FDA's Office of Device Evaluation (ODE) and Office of *In Vitro* Diagnostics (OIVD) Annual Report of approximately 2 percent for 510(k) applications filed by original equipment manufacturers. Based on this high failure rate, AdvaMed believes it is only reasonable to conclude the failure rate for reprocessed single-use devices whose validation data FDA does not intend to review could be at least as high. We believe FDA should follow through and examine all reprocessed SUDs.

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[11] Letter to Nancy Singer, Esq., then Special Counsel to the Health Industry Manufacturers Association, July 13, 1998. Reference Docket No. 97P-0377.

[12] Hearing on Reuse of Single-Use Medical Devices, Subcommittee on Oversight and Investigations of the Committee on Commerce, February 10, 2000, Serial No. 106-89; pgs. 124 & 126.

[13] See "Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single Use Medical Devices."

Branding and Labeling of Reprocessed Medical Devices

Prior to MDUFMA and the Medical Device User Fee Stabilization Act (MDUFSA), adverse events associated with reprocessed devices were frequently attributed to OEMs. Importantly, changes required by MDUFMA and MDUFSA should ensure that AEs associated with reprocessed single use devices will begin to be appropriately captured.

Prior to MDUFMA, FDA's MedWatch reporting form (used to report adverse events) failed to include a check box indicating that the device involved in the AE was a reprocessed single use device. Thus, prior to FDA's implementation of that provision in February 2004,[14] AEs associated with reprocessed single use devices were frequently mis-attributed to the OEM. Similarly, prior to MDUFSA, there was no requirement for reprocessors to mark or brand their devices. Since doctors and nurses are frequently unaware that the specific devices they are using have been reprocessed, those AEs are frequently attributed to OEMs.

MDUFSA requires reprocessors to brand their devices with their name, abbreviation or a unique and generally recognized symbol when the original manufacturer has prominently and conspicuously marked the single use device. The reprocessor can accomplish this by marking an attachment to the device. Where the OEM has not marked the device, MDUFSA requires reprocessors to use a detachable label identifying the reprocessor that is placed on the package containing the device and is intended to be placed in the patient's medical record. This provision only went into effect last month, August 2006. Therefore it is likely that the actual number of AEs associated with reprocessing will only begin to become accessible later this year.

With respect to FDA's response to the Chairman and the Ranking Member's questions about adverse events associated with the original use of the device, it is important to note that FDA did not implement the required addition of a check box indicating a reprocessed device was involved in the adverse event until February 17, 2004, 3½ months into the timeframe noted in the letter (November 1, 2003 through January 23, 2006). In addition, we are not aware of any significant efforts by FDA to educate users and providers about the existence of the new form. Finally, as noted above, the requirement for reprocessors to brand their devices has only been in place for one month. If users are unaware the device has been reprocessed, it is not clear how FDA could definitively eliminate reprocessed adverse events from the total number of adverse events during this period.

Reprocessor Allegations

Reprocessors make a number of allegations or statements regarding OEMs and reprocessing. Our responses to some of the most frequent are below.

14 See February 17, 2004 Federal Register Notice (Volume 69, Number 31), Page 7490-7492, Docket No. 2003N-0016.

FDA's adverse event database (MAUDE) reveals zero patient deaths attributed to reprocessed devices.

FDA's MAUDE database reveals numerous adverse events associated with reprocessed devices. Due to the inherent limitations associated with all adverse event reporting systems it is quite challenging to prove that a reprocessed device (or any other device or drug) was the actual cause of a patient death, serious injury or other harm. Nonetheless, the association is there. The limitations associated with adverse event reporting systems are compounded when there is uncertainty regarding whether the device is an OEM (first) use device or a reprocessor device used against the original labeling. As aforementioned, until the MDUFMA MedWatch form change and MDUFSA branding change, it would have been difficult to distinguish reprocessed devices from original single use devices.

From January 1, 2004 to the present, FDA's adverse event database contains over 6,500 reports of patient deaths associated with original (unreprocessed) devices. Because original equipment must be used if reprocessed equipment is not, it is irresponsible to report that there are alleged safety problems associated with using reprocessed equipment but fail to put this information in context by describing the safety record of original equipment.

AMDR inappropriately compares apples to oranges in an apparent attempt to overstate the safety of reprocessed devices. The correct comparison would be between single use devices and reprocessed single use devices. It is important to note that the overall number of devices used during this period alone is tremendously large. If the single use device has been reprocessed, one can only assume that the single use device was used safely in its first intended use – otherwise it would not have been placed into the reprocessing "stream" and reprocessors' validation systems should presumably have detected it. Finally, due to the relatively recent statutory changes described above, AEs associated with reprocessed single use devices may now begin to be appropriately captured.

The "single use" label is used at the OEM's discretion, often as a way to sell more devices. Indeed, "single use" does not always mean that a device is not suitable for reprocessing, as evidenced by the fact that some OEMs now reprocess their own "single use" devices, and some have changed the labels on certain "reusable" devices to "single use" without significantly changing the devices.

Single use devices are designed for optimal performance and safety under their intended conditions of use on a single patient – not ease of cleaning – and as discussed above, they typically have characteristics that make them extremely difficult to effectively clean and re-sterilize. In fact, FDA requires a single use label unless validation data demonstrates that the device can be safely cleaned, sterilized and reused. Many procedures performed today such as angioplasty or other procedures which require inserting and maneuvering devices into parts of the body that previously required open surgery cannot be done using materials that are highly durable and readily reusable. Many single use devices are manufactured of plastics, and lesser grade metals and adhesives (in order to reduce hospital purchasing costs), and the materials may not be able to be effectively cleaned and re-sterilized. Some of these materials may kink, crimp, crack or become brittle or tacky when cleaned and resterilized.

To claim that original equipment manufacturers merely re-label reusable devices as single-use in order to boost sales defies the economic basis for the single-use product market. Some commonly-used medical devices are available in both reusable and single-use configurations. This affords user institutions a logical choice based on the economics of their operation. If the institution can afford to purchase cleaning and sterilization materials and equipment and has the staff to reprocess single use devices on site (or chooses to pay an outside contractor to perform these tasks) they will purchase reusable medical devices and amortize their higher cost over a number of uses. If the user cannot afford such equipment, or does not have the staff to perform controlled cleaning and sterilization operations, they will purchase single-use devices.

However, the cost-effectiveness of this choice requires that the purchase price of the single-use device be substantially less than its reusable counterpart. Medical device manufacturers are able to meet this requirement by using lower cost materials (plastics versus metals, for example) and different designs for their single-use products. These materials and designs are nowhere near as robust or durable as those employed in reuseable devices, since they are only needed to withstand original manufacturing and a single use. Furthermore, the cost of developing a single-use device is typically lower than that for a reuseable device, since the safety and efficacy of the single use device has already been validated by the reuseable version that preceded it and the verification testing of the single use device only needs to demonstrate its ability to work once. The design of a single use device is very different from that of a reuseable device. This difference is the only way a single use device can be made available as a cost-effective option.

AdvaMed supported the MDUFMA and MDUFSA reprocessing provisions because we are interested in the appropriate regulation of these products. If appropriate regulation means some products will continue to be reprocessed because the practice is supported with appropriate validation data, then that is acceptable. If appropriate regulation of reprocessing means some of these products can no longer be reprocessed, then patient safety will benefit from that decision.

Reprocessors also routinely claim that original equipment manufacturers arbitrarily label some reusable devices as single use. This is untrue, and to date, reprocessors have failed to cite a single example of conflicting designations. Since reprocessors do not have access to the original design and material, they simply can not make this claim with any accuracy.

Obtaining informed consent from patients for the use of reprocessed "single use" devices does nothing to increase patient safety nor does it provide patients with any meaningful information about the actual risks and benefits of the medical procedures they are about to undergo. Reprocessed devices are as safe and effective as original equipment, and there is no evidence that the use of reprocessed devices increases the risks associated with a medical procedure. These are not investigational or experimental devices. It is not good or standard medical practice to obtain informed consent to use legally marketed medical devices, and there is no legal, medical or ethical basis for imposing a requirement to seek informed consent for the use of reprocessed devices but not for the use of original devices.

AdvaMed believes reprocessed single use devices may present increased risks to patients because they've been previously used in one or more patients and because single use devices typically have characteristics that make them extremely difficult to effectively clean and re-sterilize. Subsequent sterilization of previously used and cleaned single use devices may

seriously compromise their safety and performance and even destroy some single-use devices. We believe patients have the right to know and choose whether a reprocessed single use device is used in their care.

We also take issue with the reprocessors' characterization of the informed consent process. If informed consent is properly done, it does indeed provide patients with meaningful information about the actual risks and benefits of the medical procedures they may undergo.

Reprocessors are more stringently regulated than original manufacturers and as a result, reprocessed products are safer because each product is inspected before being shipped and there are no "out-of-the-box" failures.

In contrast to reprocessor assertions that they are more stringently regulated than OEMs, the MDUFMA and MDUFSA requirements simply require reprocessors to do what OEMs must already do under FDA regulations – label and brand their products as their own (something reprocessors presumably should not object to if they are confident of their products). Per MDUFMA, FDA also required a small subset of reprocessors to submit validation data demonstrating that single use devices originally intended for one use are safe and effective when reprocessed and returned to the market for additional use. As discussed above, reprocessors have previously testified to Congress that they were meeting FDA's basic regulatory requirements. However, when they were required by MDUFMA to actually demonstrate that by submitting validation data, 50% of their submissions were inadequate.

Reprocessors claim their devices are safer because each device is individually inspected. This is flawed logic because OEMs develop inspection processes that rely on the manufacturer's control of all variables (e.g., design, materials, components, and assembly). Reprocessors do not have control of all the variables that would enable them to use the statistical sampling processes used by OEMs. As a result, they must inspect each device because their history is unknown. Moreover, the final cleaned and sterilized reprocessed device cannot be individually tested without compromising the cleanliness and sterility of the product. Reprocessed devices can only be tested for functionality prior to sterilization. The integrity of the device after sterilization is therefore unknown.

Liability associated with reprocessed single use devices may be related to inherent design flaws or attributable to the OEM's own acts or omissions.

Reprocessors assume total responsibility for the single use devices they reprocess after receiving market clearance from FDA. Reprocessed devices are not the legal responsibility of OEMs. Further, if the single use device has been reprocessed, one can only assume the single use device was used safely in its first intended use – otherwise it would not have been placed into the reprocessing "stream" and reprocessor's validation systems should presumably have detected it.

Conclusion

We thank the Committee again for its interest in this important health issue. We look forward to working with Congress and the Administration on the continued implementation of the provisions in MDUFMA and MDUFSA related to the oversight of reused single-use devices.